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ART UNIT	PAPER NUMBER
1648	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/923,116	Applicant(s) MCKAY, WILLIAM F.	
	Examiner Emily Le	Art Unit 1648	

-- Th MAILING DATE of this communication appears on the cov r sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,42-49 and 51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19, 42-49, and 51-64* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *05* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

Status of Claims

The Examiner has withdrawn the restriction made by the office, 02/13/03, Paper No. 4. Claims 1-19, 42-49, and 51-64 are currently under examination. Claims 20-41 and 50 are canceled.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The submitted oath/declaration lacks the signature of the inventor. A substitute/new oath/declaration is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19, 42, 44-47, and 56-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "at least

about" in the claims is indefinite. It is unclear what the metes and bounds are of "at least about". Thus, the claims are rendered as indefinite. An amendment to the claims to read "at least" instead of "at least about" would obviate this rejection.

3. Claim 13 recites the limitation "porous particulate mineral" in line 2. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 44-47 recite the limitation "device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 46 recites the limitation "ceramic material" in line 1. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 47 recites the limitation "calcium phosphate ceramic" in line 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 3, 16, 54-55, and 63-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites "a LIM mineralization protein" and claims 16, 54-55, and 63-64 recite "BPM". It is unclear what the abbreviated terms LIM and BPM represent. An amendment to the claim to specifically spell out the abbreviated term in the first instance that it is used in its abbreviated form would obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 42, 48, 51-53, and 61-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al (U.S. Patent No. 4,888,366, "Chu").

Claim 42 recites a sponge composition comprising a carrier consisting essentially of a sponge matrix with a particulate mineral, wherein the percent of particulate mineral present in said carrier is at least about 95%; and an osteogenic factor.

Claims 48, 51-53, and 61-62 are directed toward a sponge implant (claim 48) and a sponge implant device (claims 51-53 and 61-62) comprising a resorbable matrix carrier that comprises 1%-3% of collagen, 97%-99% of mineral, and an osteogenic factor. The collagen of claim 51 is further limited telopeptide collagen. The osteogenic factor of the claims is also limited to bone morphogenic protein.

Chu teaches a sponge composition that comprises a carrier that consists essentially of sponge matrix with particulate mineral, wherein the percent of particulate mineral present is 60%-98% of said carrier and the percent of collagen, which may be atelopeptide or telopeptide (line 29-40, column 7), present is 2%-40% of said carrier; and an osteogenic factor (line 61-67, column 13). The percent of particulate mineral

present in the sponge composition taught by Chu anticipates both the at least 95% of mineral by weigh of carrier, and the percent of particulate mineral (97%-99%) and collagen (1%-3%) in carrier of the claimed invention. Further, Chu disclosed that the osteogenic factor used is bone morphogenic protein.

Chu thereby anticipates the instant invention.

9. Claims 43, 45-47, 57-59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Smestad et al (U.S. Patent No. 5,123,925, "Smestad").

Claims 43 and 60 are directed toward a sponge implant device consisting essentially of sponge matrix formed of collagen and having a particulate mineral, wherein the device comprises 1%-3% by weight of the collagen and 97%-99% by weight of the particulate mineral.

Claims 45-47 and 57-59 are further limiting of claim 43. The particulate minerals of claim 43 are further limited to synthetic ceramic, specifically calcium phosphate, more specifically biphasic calcium phosphate.

Additionally, the average particle size of the particulate mineral is limited to at least 0.5 mm, specifically 0.5mm-5mm, moreover 1mm-3mm.

Smestad teaches a sponge composition that comprises 2%-40% collagen and 60%-98% of mineral (line 45-47, column 3). The percentage of collagen and mineral used in the sponge composition anticipates the claimed invention, which comprises 1%-3% by weight of the collagen and 97%-99% by weight of the particulate mineral. The

mineral taught by Smestad is calcium phosphate, specifically biphasic calcium phosphate (line 25-30, column 4). Additionally, the particle size of the mineral taught by Smestad is in the range of 100um-200um, which is 0.1mm-2mm (line 37, column 4). The mineral and particle size taught by Smestad in making the sponge composition anticipates the limitations taught in the above claims.

Therefore, Smestad anticipates the instant invention.

With respect to the U.S.C. 35 § 102 rejections above, it is noted that the cited references do not teach that their compositions can be used in the manner instantly claimed, as a sponge implant or sponge implant device. However, the intended use of the claimed composition, a sponge implant or implant device, does not patentably distinguish the composition, a sponge composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-15 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (U.S. Patent No. 4,888, 366, "Chu") in view of Geistlich et al (U.S. Patent No. 5,573,771, "Geistlich").

The claims are directed toward a sponge composition that comprises a sponge matrix, particulate mineral, and an osteogenic factor wherein the ratio of particulate mineral to the sponge matrix is 4:1 and the average particle size of the mineral particulates is at least 0.5 mm.

The osteogenic factor of the claims is further limited to bone morphogenic protein, wherein the bone morphogenic protein is a human recombinant protein and collagen as the sponge matrix.

The weight ration of the mineral to the sponge matrix of the claims is also limited to 10:1, and 18:1 (95% by weight of the particulate mineral and 5% by weight of the sponge matrix).

Additionally, the mineral particulates of the claims are limited to bone particles, specifically cortical bone particles; and synthetic ceramics, specifically biphasic calcium phosphate, which have at least 50% porosity.

The average particle size of the mineral particulates is also limited to a range of 0.5-5 mm, preferably 1-2mm.

The claims are further limited with the addition of a growth factor selecting from a group consisting of autographic bone marrow, allographic bone marrow, transforming growth factor-β, fibroblast growth factor, platelet-derived growth factor, insulin-like growth factor, microglobulin-β, and steroids.

Lastly, the claims are limited for use in mammal and primate, specifically human.

Chu teaches a sponge composition that comprises a resorbable sponge matrix, osteogenic factor, and particulate mineral. The sponge matrix taught by Chu is collagen (line 40-65, column 14). Chu also discloses that one may derive the osteogenic factor from bones, human bones by using recombinant DNA technique. Thus, yielding a human recombinant protein (line 35-50, column 5).

Further, the particulate mineral that is used by Chu is biphasic calcium phosphate, which is a mixture of hydroxapatite (HA) and tricalcium phosphate (TCP) (line 13-18, column 7).

The weight ratio of the mineral to the sponge matrix used by Chu range from 3:2 to 44:1 (line 40-65, column 14). This range of ratio includes the ratio claimed by Applicant, 4:1, 10:1, and 18:1 (95% by weight of the particulate mineral and 5% by weight of the sponge matrix).

Chu does not teach a specific average particle size of the particulate mineral, Geistlich teaches a range of the average particle size of the mineral particulates, 0.1 mm to 10 mm (line 67, column 4). The range disclosed by Geistlich includes the range

claimed by Applicant. It would have been obvious to one of ordinary skill at the time of the claimed invention to optimize the average particle size of the mineral particulates as a matter of routine experimentation. Thus, one would have been motivated by Geistlich to optimize the average particle size of the mineral particulates of the Chu reference to increase the effectiveness of the mineral in providing a scaffold for bone ingrowth with a reasonable expectation of success.

Additionally, whereas Chu does not teach the use of mineral particulates such as bone particles, specifically cortical bone particles, Geistlich teaches the use of cortical bone particles (line 9-15, column 3). It would have been obvious to one of ordinary skill at the time of the claimed invention to substitute calcium phosphate for the cortical bone particles. Thus, one would have been motivated by Geistlich to substitute the calcium phosphate, a synthetic product, used by the Chu reference for the cortical bone particles, a product that is naturally occurring to the body, to incorporate into the collagen matrix to decrease the chances of infection or rejection of the compound when implanted into the body with a reasonable expectation of success.

Further, Geistlich teach the use of a growth factor, specifically transforming growth factors to enhance bone regeneration (line 40-43, column 6). It would have been obvious to one of ordinary skill at the time of the claimed invention to include a growth factor to enhance in bone regeneration. Thus, one would have been motivated by Geistlich to include a growth factor in the Chu reference to enhance in bone regeneration with a reasonable expectation of success.

Although neither Chu nor Geistlich teaches the porosity of the mineral, biphasic calcium phosphate, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention that biphasic calcium phosphate is an extremely porous mineral. The porosity of the biphasic mineral is dependent on the amount of each type of calcium phosphate used. McKay (U.S. Patent No. 5,702,449) teaches a biphasic calcium phosphate that has at least 50% porosity (line 56, column 8). It would have been obvious to one of ordinary skill at the time of the claimed invention to optimize the porosity of the mineral as a matter of routine experimentation. Thus, one of ordinary skill would have been motivated by McKay to optimize the porosity to permit the optimal tissue ingrowth in the Chu and Geistlich references with a reasonable expectation of success.

With respect to the U.S.C. 35 § 103 rejections above, it is noted that the cited references do not teach that their compositions can be used in the manner instantly claimed, for use in mammal and/or primate, particularly. However, the intended use of the claimed composition, for use in mammal and/or primate, particularly human, does not patentably distinguish the composition, a sponge composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art

appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

11. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu in view of Geistlich as applied to claims 1-15 and 18-19 above, and further in view of Constantz et al (U.S. Patent No. 5,231,169, "Constantz").

The claims are directed toward a sponge composition that comprises a sponge matrix, particulate mineral, and an osteogenic factor wherein the ratio of particulate mineral to the sponge matrix is 4:1 and the average particle size of the mineral particulates is at least 0.5 mm.

The claims are further limited with the addition of a growth factor selecting from a group consisting of autographic bone marrow, allographic bone marrow, transforming growth factor-β, fibroblast growth factor, platelet-derived growth factor, insulin-like growth factor, microglobulin-β, and steroids.

The osteogenic factors are limited to bone morphogenic protein (BMP), wherein the bone morphogenic protein is a human recombinant protein, wherein the BMP is BMP-2 or BMP-7.

The relevance of Chu and Geistlich are given above. Chu and Geistlich don't teach the use of BMP-2 or BMP-7, Constantz teaches the use of BMP-2 as a bone morphogenic protein. It would have been obvious to one of ordinary skill at the time of the claimed invention to use BMP-2 as the osteogenic factors as a matter of routine

experimentation. Thus, one would have been motivated by Constantz to substitute the osteogenic factor that is used in the Chu and Geistlich references with BMP-2 to promote bone growth with reasonable expectation of success.

12. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smestad as applied to claims 43, 45-47, 57-59, and 60 above, and further in view of Geistlich.

The claims are directed toward a sponge implant device consisting essentially of sponge matrix formed of collagen and having a particulate mineral, wherein the device comprises 1%-3% by weight of the collagen and 97%-99% by weight of the particulate mineral. The particulate minerals are further limited to bone particles.

The relevance of Smestad is given above. Smestad does not teach the use of bone particles as a substitute for calcium phosphate as the mineral for use in the sponge composition, Geistlich teaches the use of cortical bone particles (line 9-15, column 3). It would have been obvious to one of ordinary skill at the time of the claimed invention to substitute calcium phosphate for the cortical bone particles. Thus, one would have been motivated by Geistlich to substitute the calcium phosphate, a synthetic product, used by Smestad for cortical bone particles, a product that is naturally occurring to the body, to incorporate into the collagen matrix to decrease the chances of infection or rejection of the compound when implanted into the body with a reasonable expectation of success.

With respect to the U.S.C. 35 § 103 rejections above, it is noted that the cited references do not teach that their compositions can be used in the manner instantly claimed. However, the intended use of the claimed composition, an implant device, does not patentably distinguish the composition, a sponge composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

13. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu, Geistlich, Constantz, McKay, and Smestad as applied to claims 1-19 and 42-48 above, and further in view of Michelson (U.S. Patent No. 5,785,710).

The claim is directed to a spinal fusion implant device that comprises a load bearing member and a composition according to any of claims 1-19 and 42-48 retained by the load bearing member.

The relevance of over Chu, Geistlich, Constantz, McKay, and Smestad are provided above. Chu, Geistlich, Constantz, McKay, and Smestad does not teach the use of the sponge composition in a load bearing member as a spinal fusion implant;

Michelson teaches a spinal fusion implant device that can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material (line 20-27, column 3). It would have been obvious to one of ordinary skill at the time of the claimed invention to fill the spinal fusion implant of Michelson with an osteogenic composition. Thus, one would have been motivated by Michelson to fill the spinal fusion implant of Michelson with the osteogenic composition of Chu, Geistlich, Constantz, McKay, and Smestad to treat spinal injury with reasonable expectation of success.

14. Claims 54-55, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu as applied to claims 42, 48, 51-53, and 61-62 above, and further in view of Constantz.

The claims are directed toward a sponge implant comprising a resorbable matrix carrier comprising 1%-3% of collagen, 97%-99% of mineral, and an osteogenic factor. The osteogenic factor is bone morphogenic protein (BMP), specifically BMP-2 or BMP-7.

The relevance of Chu and Constantz are given above. Chu doesn't teach the use of BMP-2 or BMP-7, Constantz teaches the use of BMP-2 as a bone morphogenic protein. It would have been obvious to one of ordinary skill at the time of the claimed invention to use BMP-2 as the osteogenic factors as a matter of routine experimentation. Thus, one would have been motivated by Constantz to substitute the

osteogenic factor that is used in the Chu and Geistlich references with BMP-2 to promote bone growth with reasonable expectation of success.

15. Claim 56 rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (U.S. Patent No. 4,888, 366, "Chu") as applied to claims 42, 48, 51-53, and 61-62 above, and further in view of Geistlich et al (U.S. Patent No. 5,573,771, "Geistlich").

The claim a sponge composition that comprises a sponge implant device consisting essentially of sponge matrix formed of collagen and having a particulate mineral, wherein the device comprises 1%-3% by weight of the collagen and 97%-99% by weight of the particulate mineral, wherein the average particulate size of the particulate mineral is at least 0.5mm.

The relevance of Chu is given above. Chu does not teach a specific average particle size of the particulate mineral, Geistlich teaches a range of the average particle size of the mineral particulates, 0.1 mm to 10 mm (line 67, column 4). The range disclosed by Geistlich includes the range claimed by Applicant, at least 0.5mm. It would have been obvious to one of ordinary skill at the time of the claimed invention to optimize the average particle size of the mineral particulates as a matter of routine experimentation. Thus, one would have been motivated by Geistlich to optimize the average particle size of the mineral particulates of the Chu reference to increase the effectiveness of the mineral in providing a scaffold for bone ingrowth with a reasonable expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (703) 305-4452. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0169.

E.Le

James C. Housel 10/20/03

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